UNITED STATES DISTRICT COURT
THE SOUTHERN DISTRICT OF NEW YORK

ASTRAZENECA AB, AKTIEBOLAGET HÄSSLE and ASTRAZENECA LP, KBI INC. and KBI-E, INC.,	07-CV-6790 (CM)(FM)
Plaintiffs and Counterclaim Defendants,	
- against -	**ECF CASE ELECTRONICALLY FILED**
DR. REDDY'S LABORATORIES, LTD. and DR. REDDY'S LABORATORIES, INC.	**ANSWER TO THE COMPLAINT AND COUNTERCLAIMS**
Defendants and Counterclaim Plaintiffs.	

Defendants DR. REDDY'S LABORATORIES, LTD., and DR. REDDY'S LABORATORIES, INC. (collectively, "Defendants", hereinafter "DRL") answer the averments made in the numbered paragraphs of the Complaint filed on July 27, 2007, as follows:

JURISDICTION AND VENUE

1. With respect to the first sentence of paragraph 1 of the Complaint, DRL admits that this is an action for patent infringement arising under the Patent and Food and Drug Laws of the United States, Titles 35 and 21, United States Code. With respect to the second sentence of paragraph 1, DRL admits that Plaintiffs purport to base jurisdiction and venue on the specified sections of the United States Code, but DRL denies any act resulting in liability for patent infringement.

2. DRL denies the allegations in paragraph 2 of the Complaint.

3. DRL denies the allegations in paragraph 3 of the Complaint as written. DRL admits that, upon FDA approval, it intends to market is Omeprazole Magnesium Delayed Release Capsules in the United States before the expiration of the '960 and '424 patents but after the expiration of U.S. Patent Nos. 4,786,505 and 4,853,230.

4. DRL lacks information and knowledge sufficient to form a belief as to the allegations set forth in paragraph 4 of the Complaint, and therefore denies them.

5. DRL admits the allegations contained in paragraph 5 of the Complaint.

THE PARTIES

6. DRL lacks information and knowledge sufficient to form a belief as to the allegations set forth in paragraph 6 of the Complaint, and therefore denies them.

7. DRL lacks information and knowledge sufficient to form a belief as to the allegations set forth in paragraph 7 of the Complaint, and therefore denies them.

8. DRL lacks information and knowledge sufficient to form a belief as to the allegations set forth in paragraph 8 of the Complaint, and therefore denies them.

9. DRL lacks information and knowledge sufficient to form a belief as to the allegations set forth in paragraph 9 of the Complaint, and therefore denies them.

10. DRL lacks information and knowledge sufficient to form a belief as to the allegations set forth in paragraph 10 of the Complaint, and therefore denies them.

11. DRL admits the allegations contained in paragraph 11 of the Complaint.

12. DRL admits the allegations contained in paragraph 12 of the Complaint.

13. DRL admits that it is subject to personal jurisdiction in this judicial district and denies the remaining allegations contained in paragraph 13 of the Complaint.

ANSWER TO FIRST CLAIM FOR RELIEF: '960 PATENT

14. With respect to paragraph 14 of the Complaint, DRL repeats and incorporates by references paragraphs 1-13 herein.

15. DRL admits that the '960 patent, (copy attached as Exhibit A to Plaintiffs' Complaint), entitled "Pharmaceutical Formulation Of Omeprazole," was issued on November 25, 1997 to AstraZeneca AB. DRL denies the balance of the allegations contained in paragraph 15 of the Complaint.

16. DRL lacks information and knowledge sufficient to form a belief as to the allegations contained in paragraph 16 of the Complaint, and therefore denies them.

17. DRL admits the allegations contained in paragraph 17 of the Complaint.

18. DRL admits the allegations contained in paragraph 18 of the Complaint.

19. DRL denies the allegations contained in paragraph 19 of the Complaint.

20. DRL admits that its Notice of Certification does not allege invalidity of any claims of the '960 patent. DRL denies the balance of the allegations contained in paragraph 20 of the Complaint.

21. DRL admits that its Notice of Certification does not allege unenforceability or allege inequitable conduct of the '960 patent. DRL denies the balance of the allegations contained in paragraph 21 of the Complaint.

22. DRL denies the allegations contained in paragraph 22 of the Complaint.

23. DRL denies the allegations contained in paragraph 23 of the Complaint.

24. DRL denies the allegations contained in paragraph 24 of the Complaint.

25. DRL denies the allegations contained in paragraph 25 of the Complaint.

26. DRL denies the allegations contained in paragraph 26 of the Complaint.

27. DRL denies the allegations contained in paragraph 27 of the Complaint.

28. DRL admits that, in a letter dated July 3, 2007, AstraZeneca requested access to certain documents, information and samples, as well as access to DRL's ANDA No. 78-878 and the DMF. DRL lacks sufficient information and knowledge to form a belief as to the balance of the allegations contained in paragraph 28 of the Complaint.

29. DRL admits to providing product information to AstraZeneca with a letter dated July 17, 2007. DRL denies the balance of the allegations contained in Paragraph 29 of the Complaint.

30. DRL denies the allegations contained in paragraph 30 of the Complaint.

31. DRL denies the allegations contained in paragraph 31 of the Complaint.

32. DRL denies the allegations contained in paragraph 32 of the Complaint.

33. DRL denies the allegations contained in paragraph 33 of the Complaint.

ANSWER TO SECOND CLAIM FOR RELIEF: '424 PATENT

34. With respect to paragraph 34 of the Complaint, DRL repeats and incorporates by references paragraphs 1-13 herein.

35. DRL admits that the '424 patent, (copy attached as Exhibit B to Plaintiffs' Complaint), entitled "Omeprazole Magnesium Salt Form" was issued on May 4, 1999 to AstraZeneca AB. DRL denies the balance of the allegations contained in paragraph 35 of the Complaint.

36. DRL lacks information and knowledge sufficient to form a belief as to the allegations contained in paragraph 36 of the Complaint, and therefore denies them.

37. DRL admits the allegations contained in paragraph 37 of the Complaint.

38. DRL admits the allegations contained in paragraph 38 of the Complaint.

39. DRL denies the allegations contained in paragraph 39 of the Complaint.

40. DRL admits that its Notice of Certification does not allege invalidity of the claims of the '424 patent. DRL denies the balance of the allegations contained in paragraph 40 of the Complaint.

41. DRL admits that its Notice of Certification does not allege unenforceability or allege inequitable conduct of the '424 patent. DRL denies the balance of the allegations contained in paragraph 41 of the Complaint.

42. DRL denies the allegations contained in paragraph 42 of the Complaint.

43. DRL denies the allegations contained in paragraph 43 of the Complaint.

44. DRL denies the allegations contained in paragraph 44 of the Complaint.

45. DRL denies the allegations contained in paragraph 45 of the Complaint.

46. DRL denies the allegations contained in paragraph 46 of the Complaint.

47. DRL denies the allegations contained in paragraph 47 of the Complaint.

48. DRL admits that, in a letter dated July 3, 2007, AstraZeneca requested access to certain documents, information and samples, as well as access to DRL's ANDA No.

78-878 and the DMF. DRL lacks sufficient knowledge and information to form a belief as to the balance of the allegations contained in paragraph 48 of the Complaint.

49. DRL admits to providing product information to AstraZeneca with a letter dated July 17, 2007. DRL denies the balance of the allegations contained in paragraph 49 of the Complaint.

50. DRL denies the allegations contained in paragraph 50 of the Complaint.

51. DRL denies the allegations contained in paragraph 51 of the Complaint.

52. DRL denies the allegations contained in paragraph 52 of the Complaint.

53. DRL denies the allegations contained in paragraph 53 of the Complaint.

54. The remaining allegations in the Complaint are Plaintiffs' prayer for relief which do not require a response. To the extent a response is required, DRL denies that Plaintiffs are entitled to any such relief.

AFFIRMATIVE DEFENSES

Without any admission as to the burden of proof or as to any of the averments in the Complaint, DRL sets forth the following defenses:

First Affirmative Defense

The Complaint fails to state a claim upon which relief can be granted.

Second Affirmative Defense

The claims of the '960 patent are not infringed by DRL's Omeprazole Magnesium Delayed Release Capsules.

Third Affirmative Defense

The claims of the '424 patent are not infringed by DRL's Omeprazole Magnesium Delayed Release Capsules.

COUNTERCLAIMS

Dr. Reddy's Laboratories, Ltd., and Dr. Reddy's Laboratories, Inc. (collectively, "DRL") for their counterclaims against AstraZeneca AB, Aktiebolaget Hässle, Astrazeneca LP, KBI Inc. and KBI-E, Inc. (collectively "Counterclaim Defendants" or "AstraZeneca") allege and aver as follows:

PARTIES

1. Counterclaim Plaintiff Dr. Reddy's Laboratories, Ltd. is an Indian corporation, with its principal place of business at 7-1-27, Ameerpet, Hyderabad, India.

2. Counterclaim Plaintiff Dr. Reddy's Laboratories, Inc. is a New Jersey corporation, with its principal place of business at 200 Somerset Corporate Boulevard, Bridgewater, New Jersey.

3. On information and belief, Counterclaim Defendant AstraZeneca AB is a Swedish company, with its principal place of business at Södertälje, Sweden.

4. On information and belief, Counterclaim Defendant Aktiebolaget Hässle is a Swedish company, with its principal place of business at Mölndal, Sweden.

5. On information and belief, Counterclaim Defendant AstraZeneca L.P. is a Delaware limited partnership, with its principal place of business at Wilmington, Delaware.

6. On information and belief, Counterclaim Defendant KBI, Inc. is a Delaware corporation, with its principal place of business at Whitehouse Station, New Jersey.

7. On information and belief, Counterclaim Defendant KBI-E, Inc. is a Delaware corporation, with its principal place of business at Wilmington, Delaware.

JURISDICTION AND VENUE

8. This is an action for declaratory judgment pursuant to the Federal Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, together with such further and other relief that may be necessary or proper. The basis for declaratory judgment is an actual controversy between DRL and AstraZeneca arising under the United States Patent Laws, Title 35 of the United States Code. This Court has subject matter jurisdiction over the action based on 28 U.S.C. §§ 1331 and 1338.

9. This Court has personal jurisdiction over AstraZeneca in that, *inter alia*, AstraZeneca voluntarily filed, in this Court, the Complaint giving rise to this Counterclaim, and because AstraZeneca is doing business in this district.

10. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391(b) and (c) and/or 1400(b).

11. Upon FDA approval of DRL's Omeprazole Magnesium Delayed Release Capsules (equivalent to 20 mg and 40 mg of omeprazole free base) ("Omeprazole Magnesium Delayed Release Capsules"), DRL intends to market said product in the United States after the expiration of U.S. Patent Nos. 4,786,505 and 4,853,230.

12. Based upon the foregoing, as well as AstraZeneca's pattern of charging infringement of the patents asserted in the Complaint herein, an immediate and justiciable controversy exists between AstraZeneca and DRL as to the non-infringement of the patents presently in suit and as to the effective date of approval of DRL's ANDA under Section 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355 (j)) for DRL's Omeprazole Magnesium Delayed Release Capsules. DRL requires an immediate declaration of its right vis-à-vis AstraZeneca with respect to the patents presently in suit.

THE PATENTS IN SUIT

13. U.S. Patent No. 5,690,960 ("the '960 patent"), entitled "Pharmaceutical Formulation of Omeprazole," issued on November 25, 1997. The named inventors are Inga Siv Bengtsson and Kurt Ingmar Lövgren. The listed assignee is Astra Aktiebolag, now known as AstraZeneca AB.

14. U.S. Patent No. 5,900,424 ("the '424 patent"), entitled "Omeprazole Magnesium Salt Form," issued on May 4, 1999. The named inventors are Lars Åke Källström and Monica Annelie Nygren. The listed assignee is Astra Aktiebolag, now known as AstraZeneca AB.

15. On information and belief, AstraZeneca AB is the current owner by assignment of the '960 and '424 patents. On information and belief, KBI Inc. and KBI-E, Inc. have exclusive rights in the United States to the '960 and '424 patents.

FIRST COUNTERCLAIM

Declaratory Judgement of Non-infringement of the Claims of the '960 Patent

16. DRL repeats and realleges the allegations contained in paragraphs 1-15 as if fully set forth here.

17. This counterclaim is for a declaration that DRL's Omeprazole Magnesium Delayed Release Capsules do not infringe any of the claims of the '960 patent.

18. There is an actual, substantial and continuing justiciable case or controversy between DRL and AstraZeneca regarding the non-infringement of the '960 patent.

19. The manufacture, use, sale, offer for sale, and/or importation of the

Omeprazole Magnesium Delayed Release Capsules that are the subject of DRL's ANDA No. 78-878 have not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '960 patent.

20. DRL is entitled to a judicial declaration that the manufacture, use, sale, offer for sale and/or importation of the Omeprazole Magnesium Delayed Release Capsules that are the subject of DRL's ANDA No. 78-878 have not infringed, do not infringe, and would not, if marketed, infringe any valid claim of the '960 patent.

SECOND COUNTERCLAIM

Declaratory Judgment of Non-infringement of the Claims of the '424 Patent

21. DRL repeats and realleges the allegations contained in paragraphs 1-15 as if fully set forth here.

22. This counterclaim is for a declaration that DRL's Omeprazole Magnesium Delayed Release Capsules do not infringe any of the claims of the '424 patent.

23. There is an actual, substantial and continuing justiciable case or controversy between DRL and AstraZeneca regarding the non-infringement of the '424 patent.

24. The manufacture, use, sale, offer for sale, and/or importation of the Omeprazole Magnesium Delayed Release Capsules that are the subject of DRL's ANDA No. 78-878 have not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '424 patent.

25. DRL is entitled to a judicial declaration that the manufacture, use, sale, offer for sale and/or importation of the Omeprazole Magnesium Delayed Release Capsules that

are the subject of DRL's ANDA No. 78-878 have not infringed, do not infringe, and would not, if marketed, infringe any valid claim of the '424 patent.

WHEREFORE, DRL respectfully requests that this Court:

(a) Dismiss the Complaint against DRL with prejudice and that Plaintiffs and Counterclaim Defendants take nothing thereby;

(b) Declare that DRL's Omeprazole Magnesium Delayed Release Capsules do not infringe any of the claims of the '960 and '424 patents;

(c) Declare that this is an exceptional case within the meaning of 35 U.S.C. § 285 since Plaintiffs and Counterclaim Defendants knowingly brought this baseless action merely to invoke the statutory 30 month stay;

(d) Award DRL its attorney fees and costs in this suit; and

(e) Award such other and further relief as this Court may deem just and proper.

Respectfully submitted,

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and Counterclaim Plaintiffs
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By: /s/ Bruce D. Radin
Andrew J. Miller (AM 8160)
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Dated: August 16, 2007